DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

5184

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

WARNING LETTER

February 9, 2001

CERTIFIED MAIL – RETURN RECEIPT REQUESTED

Brian J. Turney, CEO
Kingman Regional Medical Center
3269 Stockton Hill Road
Kingman, AZ 86401

WL 21-01

Dear Mr. Turney:

During an inspection of your unlicensed blood bank and transfusion service located in Kingman, AZ, conducted December 6 through 8, 2000; FDA investigators documented violations of current Good Manufacturing Practices (cGMP, Title 21, Code of Federal Regulations (CFR), Part 210, 211 and 600 through 680) that cause all blood products collected, processed, compatibility tested or stored at your facility to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act). The violations from cGMP include:

1. Failure to establish and maintain a quality control unit in that there are no written quality control procedures [21 CFR §211.22 (d)], there is no designated individual (or individuals) who has the responsibility to ensure that blood products have the requisite safety, purity, potency or effectiveness before release [21 CFR §211.22(a)], and there is no designated individual (or individuals) responsible for approving or rejecting procedures and specifications affecting the safety, purity, potency or effectiveness of the whole blood products collected, processed, stored and compatibility tested at your facility [21 CFR §211.22(c)].

2. Failure to establish, maintain and/or follow Standard Operating Procedures which include all significant steps in the collection, processing and storage of blood and blood components [21 CFR §606.100(b)] in that you have no procedure for: handling and investigating donor adverse reactions, determining donor suitability, reporting fatal donor and transfusion related adverse reactions, establishing what constitutes a long draw to prevent activation of the coagulation system (draws of 28, 25 and 30 minutes were documented), and identifying and investigating deviations or errors and accidents that occur during the collection, processing and storing of blood products and components.

3. Failure to review all records pertinent to the unit prior to release [21 CFR 606.100(c)] in that there was no documented evidence that the following records were reviewed: donor suitability records, daily reagent QC, equipment maintenance and calibration, daily temperature QC, transfusion service and compatibility testing records.

4. Failure to concurrently record the performance of each significant step [606.160(a)] in that the start and stop bleed times are not routinely recorded on the [redacted] form.

5. Failure to store Fresh Frozen Plasma at ≤ -18 deg. C [640.34(b)] in that there were several documented instances where the temperature of the [redacted] freezer, as recorded on the temperature recorder, was greater than –18 deg. C over the past year without explanation or investigation.

6. Failure to maintain equipment on a regularly scheduled basis [21 CFR 606.60(a)] in that gaps were observed in the temperature recordings from the [redacted] freezer on multiple occasions in 2000.

7. Failure to calibrate equipment at the minimum frequency required [21 CFR 606.60(b)] in that the electronic thermometers used for daily monitoring of the [redacted] freezer have not been calibrated.

The above listed violations are not intended to be an all-inclusive list of deviations which may exist at your facility. It is your responsibility to ensure that that your blood establishment is in full compliance with the Act and regulations promulgated thereunder. You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in further regulatory action without further notice, which may include Order for Retention, Recall and/or Destruction, and/or Injunction.

Please notify this office in writing, within fifteen (15) working days of your receipt of this letter, of the specific steps you have taken to correct the noted deviations and to prevent their recurrence. If corrective action cannot be completed within fifteen working days, please state the reason for the delay, and the time within which corrections will be completed.

Your reply should be directed to the Food and Drug Administration, Attention:

Thomas L. Sawyer
Director, Compliance Branch
Food and Drug Administration
19900 MacArthur Blvd., Suite 300
Irvine, CA 92612

Sincerely,

Irene Gomez

Irene Gomez
Acting District Director